What has the Department of Defense (DoD) seen in terms of <u>heart inflammation</u> after smallpox vaccination?

The Department of Defense reported its first case of inflammation in or around the heart (myo-pericarditis) after smallpox vaccination in early February 2003. DoD identified several cases of myocarditis and/or pericarditis among 350,000 smallpox vaccinees, with symptoms appearing 7 to 19 days after vaccination. These people had clinical conditions that varied from mild to severe. They all survived. They have been discharged from hospital, and have either returned to duty or been given short-term convalescent leave to regain their strength.

Each case occurred among those receiving smallpox vaccination for the first time. None occurred among those receiving re-vaccination.

The health of our people is foremost in our priorities. We will continue to monitor these people for the next year to ensure they receive the care they need and deserve. Based on European experience, we have reason to believe these people should recover and remain well.

What is the difference between myo-pericarditis, myocarditis, and pericarditis?

Myocarditis is an inflammation of heart muscle tissue (the myocardium). Pericarditis is an inflammation of the sac surrounding the heart (the pericardium). When both conditions occur at the same time, it is called myo-pericarditis.

Is there a relationship between the recently reported heart attacks and DoD's findings of myocarditis and/or pericarditis in smallpox vaccinees?

Myocarditis and heart attacks are different diseases. Myocarditis involves inflammation of the heart muscle. Heart attacks are different, in that they involve problems with heart rhythm or blood vessels in the heart. At present, we don't see evidence of a link between myocarditis and heart attacks. But our minds are open and we continue to look into it.

How does smallpox vaccine cause myocarditis or pericarditis?

The precise cause is unknown. However, a reasonable theory is that the vaccinia virus in smallpox vaccine gets into the blood stream and then causes inflammation in some heart tissue.

Was the finding of myo-pericarditis a surprise to DoD officials? Is this a new or previously unknown reaction?

Because rare cases of myo-pericarditis have been reported previously following smallpox vaccination, notably in a study of Finnish military recruits in the 1980s, DoD was watching for the occurrence of myocarditis and was not surprised. In Finland, 1 per 10,000 vaccinees developed myo-pericarditis.

How was the myocarditis or pericarditis diagnosed in service members?

The patients with myocarditis and/or pericarditis sought medical care after developing chest pain. Blood tests showed that they had elevated levels of enzymes (such as CKMB or troponin), suggesting myocarditis or pericarditis. They had temporary changes in ECG (electro-cardiogram) and/or echo-cardiogram readings.

Has the military seen any heart attacks in people vaccinated against smallpox?

Yes. A 55-year-old servicemember died 5 days after smallpox vaccination. We regret the death of any servicemember, whatever the reason. Based on our investigation of medical records and autopsy findings, the Department of Defense does not consider smallpox vaccination likely to be the cause of death, based on pre-existing heart disease. Additional testing at the Armed Forces Institute of Pathology confirmed this finding.

Several other cases of cardiovascular disease have occurred among smallpox-vaccinated people. These appear to be occurring at rates similar to what is expected among unvaccinated people. We will provide more information when available.

Between 1998 and 2000, before the DoD Smallpox Vaccination Program began, an average of 150 active-duty servicemembers were admitted each year to DoD hospitals for heart attacks. Each year in DoD, several dozen active-duty personnel die of heart disease. In the Total Army (Active, Guard, and Reserve), roughly 50 deaths due to heart conditions occur each year.

Heart pain (angina) and heart attack also have been reported in the civilian smallpox vaccination program, largely among people 50 years and older. It is not known if smallpox vaccination caused these problems or if they occurred by chance alone (heart problems are very common). For more information on the civilian program, go to www.bt.cdc.gov.

Will DoD defer from smallpox vaccination people who have had heart conditions?

Yes. We will defer people with serious heart- or vessel-related conditions. Importantly from the standpoint of military readiness, people with major heart conditions are unlikely to be in military service. Some examples include a history of angina, an earlier heart attack, artery disease, congestive heart failure, cardiomyopathy, stroke, "mini stroke," or chest pain or shortness of breath with activity (such as walking up stairs). If you have concerns about your health history, speak with your health care provider before vaccination.

Similar to the CDC, and based on input from the American College of Cardiology, we will also defer people with three or more cardiac risk factors. The risk factors include:

- (1) current smoker,
- (2) high blood pressure,
- (3) high cholesterol,
- (4) high blood sugar, and
- (5) a heart condition before age 50 in a parent, brother, or sister.

Vaccination of other people should continue as planned.

If you smoke, we encourage you to stop.

I recently received the smallpox vaccination, and I have a history of heart conditions. What should I do?

Unless you start displaying symptoms such as chest pains, difficulty breathing, shortness of breath, or pain radiating down arm or to neck, you shouldn't do anything special. If you start having these symptoms, you should seek medical care right away.

What about people who had a smallpox vaccination when they were younger, and then later had a heart attack or heart condition? Should these people be deferred?

Yes, if someone has a history of a serious heart condition, he or she should be deferred from receiving smallpox vaccine in a non-emergency situation.

If somebody with a serious heart condition is exposed to the disease smallpox, should they get the smallpox vaccine?

In most cases, experts agree that people directly exposed to the disease smallpox (i.e., variola virus) should get the smallpox vaccine. In an emergency situation, this would apply to people with serious heart conditions.